

**Notice of Allowability**

Application No.

09/905,704

Examiner

Valarie Bertoglio

Applicant(s)

HERRON, G. SCOTT

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 09/02/2003.
2. ☒ The allowed claim(s) is/are 1-5, 7-15, 17-30.
3. ☒ The drawings filed on 27 February 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                         |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 6 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>11/21&amp;24</u> . |
| 3 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No. <u>01/13/2003</u> | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                                 |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                       | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance                           |
|   | 9 <input type="checkbox"/> Other   |

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Narinder Benait on November 21, 2003.

The application has been amended as follows:

In the specification:

Please amend the specification by replacing the paragraph beginning page 1, line 6, with the following paragraph:

This application claims priority under 35 U.S.C 119(e) from United States Provisional Application Serial No. 60/271,778, filed 02/27/2001.

In the claims:

Please amend the claims as follows:

1. An in vivo assay system for determining the effect of a pharmaceutically acceptable compound on angiogenesis comprising:
  - a. a composition of human endothelial cells; and
  - b. a non-human, immuno-compromised host,wherein said cells have a recombinant expression cassette encoding telomerase.
2. The in vivo assay system of claim 1 further comprising a digital imaging device.
3. The in vivo assay system of claim 2 wherein said device detects fluorescence.
4. The in vivo assay system of claim 1 wherein said cells express a genetic marker.

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5. The in vivo assay system of claim 4 wherein said genetic marker is enhanced green fluorescent protein (eGFP).
6. cancel
7. The in vivo assay system of claim 1 wherein said telomerase is a human telomerase reverse transcriptase catalytic subunit.
8. The in vivo assay system of claim 1 wherein said host is a SCID mouse.
9. The in vivo assay system of claim 1 wherein said compound is selected from the group consisting of growth factors, extracellular matrix molecules, proteinase inhibitors, cell adhesion molecules, angiostatic factors, apoptotic inducers, and inflammatory mediators.
10. The in vivo assay system of claim 9 wherein said compound is a growth factor.
11. The in vivo assay system of claim 10 wherein said growth factor is selected from the group consisting of angiopoietins, CTGF, EGF, FGF-2, IGF, PLGF, PDGF, SF, TGF, and VEGF.
12. The in vivo assay system of claim 11 wherein said growth factor is VEGF.
13. The in vivo assay system of claim 11 wherein said growth factor is FGF-2.
14. The in vivo assay system of claim 1 wherein said compound is capable of modulating tumor angiogenesis.
15. An in vivo method for analyzing the effect of a pharmaceutically acceptable compound on angiogenesis comprising:
  - a. providing a composition comprising human endothelial cells, wherein said cells have a recombinant expression cassette encoding telomerase and a genetic marker;
  - b. adding a compound to said composition;
  - c. implanting said composition in a non-human, immuno-compromised host; and
  - d. determining the amount of angiogenesis in the implanted cells by measuring the expression of said genetic marker.
16. cancel
17. The in vivo method of claim 15 wherein said telomerase is a human telomerase reverse transcriptase catalytic subunit.
18. The in vivo method of claim 15 wherein said genetic marker is enhanced green fluorescent protein (eGFP).

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19. The in vivo method of claim 15 wherein expression of said genetic marker is detected by a digital imaging device.
20. The in vivo method of claim 15 wherein said compound is selected from the group consisting of growth factors, extracellular matrix molecules, proteinase inhibitors, cell adhesion molecules, angiostatic factors, apoptotic inducers, and inflammatory mediators.
21. The in vivo method of claim 20 wherein said compound is a growth factor.
22. The in vivo method of claim 21 wherein said compound is VEGF.
23. The in vivo method of claim 21 wherein said compound is FGF-2.
24. The in vivo method of claim 15 wherein said composition further comprises matrigel.
25. The in vivo method of claim 15 wherein said host is a SCID mouse.
26. The in vivo method of claim 15 wherein said compound is capable of modulating tumor angiogenesis.
27. A non-human, immuno-compromised host comprising at least one capillary, venule or arteriole formed from a composition of human endothelial cells having a recombinant expression cassette encoding telomerase, and a genetic marker, wherein blood of said host is transmitted through said at least one capillary, venule or arteriole.
28. The non-human immunocompromised host of claim 27 wherein said host is a SCID mouse.
29. The non-human immunocompromised host of claim 27 wherein said telomerase is a human telomerase reverse transcriptase catalytic subunit.
30. The non-human immunocompromised host of claim 27 wherein said genetic marker is enhanced green fluorescent protein (eGFP).

The following is an examiner's statement of reasons for allowance:

Applicant narrowed the scope of the claimed subject matter to immuno-compromised hosts, overcoming the enablement rejection. Applicant's arguments with respect to the rejection of claims 1-10, 15-21, 24 and 25 under 35 USC 103(a) are persuasive and the rejection is withdrawn. It would not have been obvious for one of skill in the art to apply the technology

known in the art for immortalizing adrenocortical cells to human endothelial cells and implanting said cells into a non-human host.


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on Mon-Weds 6:00-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Valarie Bertoglio  
Examiner  
Art Unit 1632



MICHAEL WILSON  
PRIMARY EXAMINER